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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,020	09/18/2006	Frederic Ben	58767.000017	3183

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WASHINGTON, DC 20006-1109

EXAMINER
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LISTVOYB, GREGORY

ART UNIT	PAPER NUMBER
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1765

MAIL DATE	DELIVERY MODE
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12/07/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,020	<b>Applicant(s)</b> BEN ET AL.	
	<b>Examiner</b> GREGORY LISTVOYB	<b>Art Unit</b> 1765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-27, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18-27 and 34 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18-27 and new claim 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al (US 6355772) in view of Bowman (US 3047524) as evidences by Nevin et al (US 4273920). ) (all cited in the previous Office Action)

Gruber teaches a catalytic system, which contains a strongly acidic ion-exchange polymeric catalyst Amberlist 36 (see Example 8, Column 20, line 55, meeting the relevant limitations of claims 16 and 19-21).

In addition, Gruber teaches an alcohol as a part of reaction mixture (see Column 15, line 5), which used for molecular weight control, meeting the relevant limitations of claims 22-26.

In reference to new claim 34, Gruber discloses degree of polymerization of less than 30 (see Example 8).

Gruber does not teach both components in one catalytic system.

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The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to use Amberlist 36 and alcohol together in one catalytic system. The above compounds fulfill different functions of catalyzing polymerization and regulating its molecular weight.

Gruber does not teach the nature and amount of alcohol used.

Bowman teaches a polymerization of glycolic acid, which is analogous to polymerization of lactic acid disclosed by Gruber.

Bowman teaches an addition of 1-5 mol percent (see Column 2, line 10) of a monohydric aliphatic alcohol , such as methanol, ethanol or hexanol (see Column 1, line 40) or, in general, aliphatic alcohol containing 1-6 carbon atoms (see Column 1, line 40) in order to produce a polymer with desired properties.

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Regarding the newly added limitation claiming "the quantity of the one or more lactide and/or glycolide monomer(s), relative to the quantity of (co)oligomerization additive ranges from 2 to 30 molar equivalents", Gruber teaches that the amount of molecular weight control agent should be sufficient to control a molecular weight within the range of 10000 to 300000 (see Column 15, line 10).

As evidences by Nevin the process for synthesis of lactic-glycolic copolymer in melt and solution at the presence of acidic ion-exchange resin produces a polymer with Molecular weight within the range of 6000-35000. (see Abstract).

It has long been an axiom of United States patent law that it is not inventive to discover the optimum or workable ranges of result-effective variables by routine experimentation. In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Boesch, 617 F.2d 272,276 (CCPA 1980) ("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."); In re Aller, 220 F.2d 454,456 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."). "Only if the 'results of optimizing a variable' are 'unexpectedly good' can a patent be obtained for the claimed critical

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range." In re Geisler, 116 F.3d 1465, 1470 (Fed. Cir. 1997)(quoting In re Antonie, 559 F.2d 618, 620 (CCPA 1977)).

Therefore, it would have been obvious to a person of ordinary skills in the art to add 1-5 mol percent of aliphatic alcohol containing 1-6 carbon atoms to Gruber's system at the suitable amount in order to obtain a polymer with desired properties (i.e. required molecular weight).

Regarding newly added claim 33, both Gruber and Nevin disclose a systems free of metal catalyst (see Example 8 of Gruber and Abstract of Nevin).

### ***Allowable Subject Matter***

Claim 33 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Prior art fails to disclose catalytic system of claim 16, where monomer conversion exceeds 95%.

The closest prior art is Gruber (see Example 8 and Table 7). However, the reference above discloses only 73.5% conversion.

***Response to Arguments***

Applicant's arguments filed 3/16/2010 have been fully considered but they are not persuasive.

Applicant argues that since polymer in Gruber's application has a low molecular weight, when produced with ion-exchange resin, the molecular weight control agent is not needed.

However, polylactide polymer, produced with acidic ion-exchange resin may have broad range of molecular weights. In fact, Nevin teaches the process takes place at the presence of acidic ion-exchange resin, where the polymer has molecular weight within the range of 600-35000.

Additionally, in Example 8 Gruber demonstrates much higher monomers conversion for the polymer obtained with strong acidic catalyst compare to the common one.

Note that this argument was made in the Office Action dated on 3/16/2010.

Applicant argues that Gruber's process represents ring opening polymerization, whereas Bowman and Nevin disclose direct polymerization process.

However, the above observation demonstrates versatility of the acidic catalytic system, showing its applicability for both forms of lactic acid.

(Typical lactic acid polymerization includes dehydration step, where the acid forms intermediate lactide cycle. Nevin demonstrates that lactic and glycolic acids can be successfully polymerized without dehydration step, which can create economically sound process. It would be an additional motivation for an artisan to use strongly acidic catalytic system).

Examiner agrees with Applicant regarding conversion of lactic acid at the presence of highly acidic catalyst. Therefore, new claim 33 is objected (see discussion above).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone



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number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GL  
/GREGORY LISTVOYB/  
Examiner, Art Unit 1765

Applicant submits that Gruber does not teach newly claimed amount of molecular weight control agent.

However, Gruber suggests that that the amount of molecular weight control agent should be sufficient to control a molecular weight within the range of 10000 to 300000 (see Column 15, line 10). This amount is dictated by aimed molecular weight and can be determined in the course of routine experimentation (see discussion above).